REMARKS

Claims 1-18 are of record pending in this case and stand rejected. Claim 15 is objected to. No claims are currently added or canceled. Claim 15 is currently amended. Accordingly, claims 1-18 remain pending in the application. Reexamination and reconsideration of claims 1-18 are respectfully requested.

Note, no new matter is believed to be added herein. Moreover, any matter cancelled or otherwise no longer in the present claims due to amendment, cancellation or otherwise is intended to be so cancelled or otherwise outside the present scope without prejudice to potential pursuit through continuation or otherwise.

Information Disclosure Statement

Applicants note with appreciation the acceptance of the IDS received on February 23, 2009.

Claim Objections

Applicants note that claim 15 was objected to as allegedly being in improper multiple dependent form, but has nevertheless been examined. Claim 15 has been amended hereby and the objection is thus moot relative thereto. Withdrawal of the objection is thus respectfully requested.

Claim Rejections 35 U.S.C. § 112

Applicants note with appreciation the withdrawal of the rejections of claims 5, 6, 13, 14, 16 and 17 for a variety of specific alleged informalities under 35 USC § 112.

Rejections Under 35 U.S.C. § 103

Applicants note with appreciation the withdrawal of the rejection of what appears to be all of claims 1-18 under 35 USC §103(a), as purportedly being unpatentably obvious over various uses of Birmingham et al. (U.S. Patent No. 5,989,824; hereinafter "Birmingham") in view of Mainelis et al. (Reference number 56 from the IDS of January 25, 2007; hereinafter "Mainelis"), firstly, for claims 1, 2 and 17; and over Birmingham in view of Mainelis and further in view of Johns, et al. (Reference number 47 from the IDS of January 25, 2007; hereinafter "Johns") for claims 3, 4, 7-9, 13-15 and 18; and apparently also over Birmingham in view of Mainelis and further in view of Braven, et al. (Reference number 34 from the IDS of January 25, 2007; hereinafter "Braven") for claims 5, 6, 10-12 and 16. On and as to claims 5, 6, 10-12 and 16, Applicants appreciate that an apparent typographical error appears in the Office Action of 5/19/2009, page 3, lines 10-14, where it appears that the rejection of claims 5, 6, 10-12 and 16 was intended to be withdrawn over Birmingham, Mainelis and Braven. Acknowledgment of the error and confirmation that there is indeed no current rejection of claims 5, 6, 10-12 and 16 over Birmingham, Mainelis and Braven is respectfully requested.

Claims 1, 2, and 17 are now rejected under 35 U.S.C. §103(a) as purportedly being unpatentable over Huang et al. (Analytical Biochemistry, 2002, vol. 372, pages 49-65) in view of Mainelis and Birmingham. Claims 3, 4, 7-9, 13-15, and 18 are rejected as purportedly being unpatentable over Huang, in view of Mainelis and in further view of Johns. Claims 5, 6, 10-12 and 16 are rejected under 35 U.S.C. §103(a) as purportedly being unpatentable over Huang in view of Mainelis, Birmingham, and Braven.

Applicants respectfully note the obviation of and/or respectfully traverse these rejections for at least the reasons discussed below.

In short and as will be shown, Huang does not cure the deficiencies of the art of Birmingham and Mainelis whether alone or in further combinations with Johns and/or Braven.

Claims 1, 2 and 17

More particularly, claims 1, 2 and 17 stand rejected under 35 USC §103(a), as allegedly being obvious over Huang in view of Birmingham and Mainelis. Mainelis and Birmingham were discussed at length in the previous action response, and the lackings of the combination thereof is not here cured by Huang, which is newly introduced here.

Huang discloses micro- electromechanical systems for sample preparation and DNA analysis of water-based samples. Huang describes the use of dielectrophoresis for cell separation performed on aqueous samples. Dielectrophoresis is very different from the electrostatic particle collection of the Applicants' presently claimed developments. Dielectrophoresis makes use of alternating electric fields and makes it possible to manipulate particles in an aqueous sample. Conversely, the electrostatic particle collection of the Applicants' developments involves gaseous samples and capture of the biological particles using electrostatic forces, which are quite different from dielectrophoretic forces.

Dielectrophoresis would not likely work at all in a gas sample. Applicants are not aware of any examples of dielectrophoretic particle capture from a gas phase. Additionally, the electrode design which normally is used for dielectrophoresis, planar electrode array located on the same side of a chamber, is unsuitable for electrostatic particle capture in gas samples.

As the Office Action points out, Huang does **not** disclose:

- The first and second electrode
- The distance of at most 20 mm between the first and second electrode
- Electrostatic collection of particles from a gaseous sample
- A gaseous sample
- Contacting electrostatically collected biological particles with the first liquid reagent

An additional difference, which has not yet been noticed, is that Huang also does not disclose:

- The concept of electrostatically collecting and lysing the biological particles in the same chamber.

The Office Action states that "It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Huang et al. with the teachings of Mainelis et al., and Birmingham et al., thereby arriving at the claimed invention.." Office Action of May 19, 2009, page 5, fifth full paragraph.

However, there are irreconcilable incompatibilities between Huang and Mainelis which would prevent one skilled in the art from making such a combination.

Applicants have discussed Mainelis at length in Applicants' previous Response to Office Action, dated February 23, 2009. Specifically, Mainelis only describes macro-size chambers and does not describe or suggest how to arrive at a micro-electrostatic collection device. Furthermore, the system of Mainelis requires a collection medium for capturing or retaining the biological particles. Examples of these collection media are agar, water, or filter paper. If the biological particles captured in the system of Mainelis should be further analyzed, it would require transferring a portion of collection medium (agar, water, or filter paper) to another device and performing the analysis there.

However, both Huang and Mainelis are entirely silent as to how one could make such an interface between a capture device and a lysis/analysis device. Consequently, one skilled in the art would not be able to arrive at the claimed subject matter without performing **inventive modifications** of the disclosures of Mainelis and/or Huang. Enablement is an issue for rejections under 102 and 103, particularly if the alleged combination cannot be produced from the art without undue experimentation. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003). For section 103, this is what teaching, suggestion and/or motivation are about (retained by the KSR Supreme Court decision); what and/or how does the art teach, suggest or motivate the change? If the change is not taught, suggested or motivated by the art, then it is not obvious.

Here, the chances of success of implementing the disclosure of Mainelis in a microsystem as described by Huang are even poorer than from the combination of two separate devices. Huang neither teaches nor suggests how one should implement the Mainelis agar, water or filter paper to arrive at a functional microsystem, which is capable of electrostatic collection, lysis, and DNA analysis.

One feature of the Applicants' claim 1 is that the biological particles are electrostatically collected from the gaseous sample, contacted with the first liquid reagent and lysed using an alternating electric field all in the same sample chamber. Applicants have noted that performing these process steps in the same chamber is particularly advantageous since it makes the design of the chip and the overall liquid handling more robust and simple.

As Mainelis does not disclose lysis or subsequent DNA analysis and as Huang does not disclose electrostatic collection of particles, the combination of the two documents and/or the teachings thereof could/would not lead one skilled in the art to a method where the biological particles are electrostatically collected from the gaseous sample, contacted with the first liquid reagent and lysed by means of an alternating electric field all in the same sample chamber. Consequently, one skilled in the art could not arrive at the claimed subject matter without performing inventive modifications of the disclosures of Mainelis and/or Huang.

As to Birmingham, and particularly as to the allegation of the motivation coming from Birmingham for the combination of Mainelis with Huang, this is at a basic level not the sort of motivation that section 103 uses. A mere conclusion, as in Birmingham, that it would be a good thing to achieve a "portable … device" that has multiple capabilities is not enough to suggest or motivate particularly that Mainelis and Huang be combined. The suggestion or motivation must come from or be specifically associated with the art being combined in such a manner as to demonstrate how the two discrete systems can be put together. The mere conclusion from Birmingham does nothing to establish how Mainelis could or would be modified to work with Huang, or vice versa. This is not section 103 motivation.

Further details on Birmingham: Applicants previously noted that Birmingham does not have "first and second [] electrode[s]" to provide an "electric field" and for "exposing [the biological particle] reaction mixture to an alternating electric field"; nor does Birmingham provide for "contacting the collected biological particle with a first liquid reagent"; Applicants' claim 1, elements a, c, d and e, emphasis added. Birmingham rather uses "ionized discharges" and "gases"; not electrodes, electric fields and liquids. Thus, Birmingham does not therefore teach or suggest the purported corresponding elements of Applicants' claims and consequently does not provide a proper basis for rejection under section 103, whether on its own or in view of Huang and/or Mainelis.

As set forth prior, Mainelis does not cure the lacking of Birmingham in also not disclosing or suggesting a substitution to or change from the Birmingham system toward "a liquid reagent" or "electrodes" with an "electric field" therebetween. There is no motivation to or from either Birmingham or Mainelis to substitute two electrodes and an associated electric field therebetween for an ionizing discharge generator (Birmingham doesn't suggest that it may have or want a substitute for the ionizing discharge generator, and Mainelis doesn't suggest adaptation of its electrodes into a system like Birmingham's). Moreover, there is no suggestion, nor assertion to achieve a liquid reagent mixture by asserted combination of Mainelis with Birmingham. Mainelis is not even asserted for such a purpose. Birmingham fails to enable a liquid, and Mainelis is not asserted to cure this failure.

In short, this situation is not one of simple substitution, nor is it one of a simple 'upgrade'. See, cf., KSR, supra at ___, 82 USPQ2d at 1399 (discussing 'upgrading Asano with a sensor'). Applicants' presently claimed developments involve a combination, not subject to nor being a simple addition, replacement, mounting or an upgrade from any of Huang, Mainelis, or Birmingham. In the instant case, a person of ordinary skill in the art having common sense at the time of the invention would not have reasonably looked to Huang to solve a problem not even announced in or by any of Huang, Birmingham or Mainelis. An artisan having common sense at the time of Applicants' developments would not even be concerned with any possible failings of the ionizing discharge generator of Birmingham, let alone how or why such might be replaced using a substitute set of electrodes whether like those in Mainelis or otherwise; let alone from

where and in what manner such skilled persons might be directed to use of a liquid reagent, nor would this artisan have looked to Huang for its passing mention of the possibility that cells can be electrically lysed, without any further explanation. Thus, Applicants respectfully submit that the rejection of claims 1, 2 and 17 on Huang, Birmingham and Mainelis fails.

Thus, there is no motivation or suggestion for combination of Birmingham with Mainelis to result in Applicants' claimed subject matter, as particularly set forth in independent claim 1 as well as all claims dependent therefrom, including dependent claims 2 and 17, and thus, such alleged combination fails to render obvious Applicants' claims having such. Claims 1, 2 and 17 are thus patentable over Birmingham in view of Mainelis. The rejections of claims 1, 2 and 17 are thus obviated or traversed and can and should be withdrawn. Action to this end is respectfully requested.

Claims 3, 4, 7-9, 13-15 and 18

Similarly, claims 3, 4, 7-9, 13-15 and 18 stand rejected under 35 USC §103(a), as purportedly being obvious over Huang in view of Mainelis and Birmingham and further in view of Johns.

And, as was the case for Huang, Birmingham and Mainelis in the previous section, Johns does not cure the initial and basic lackings of these three references; and, indeed, it was not even asserted for such purpose. Thus, for the same reasons Mainelis and Birmingham failed to sufficiently supplement Huang; all such reasons being incorporated herein as if fully set forth here, Johns also fails to provide all of the missing elements presented in Applicants' claims and thus Applicants' claims are patentable hereover. There is still no teaching or suggestion of the two electrode electric field nor of a liquid reagent in the currently claimed combinations. This rejection must thus be withdrawn.

Moreover, Applicants do also hereby challenge and respectfully request art citations for the assertion of official notice for the alleged teaching of miniature PCR with particularly any relevance hereof toward and/or teaching/suggestion or motivation therefrom toward the presently-claimed subject matter. Applicants cite Zurko and/or Rule 104 for this purpose.

An Examiner taking "Official Notice" of the basic knowledge or common sense of a person of ordinary skill in the art to supplement the specific teachings of the art, must provide some form of evidence in the record to support such an assertion of common knowledge. In re Zurko, 258 F.3d 1379, 1386, 59 U.S.P.Q.2d 1693, 1697 (holding that general conclusions concerning what is "basic knowledge" or "common sense" to one of ordinary skill in the art without specific factual findings and some concrete evidence in the record to support these findings will not support a rejection). Moreover, if the Examiner relies on his or her personal knowledge to supplement what is actually known in the art, the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the supplementation. 37 CFR 1.104(d)(2).

The Examiner provides no evidence or affidavit supporting the Examiner's apparent taking of Official Notice of the Examiner's assertion that "the art is replete with miniature devices for conducting PCR, which comprises heating electrode and temperature sensing elements". In response to this taking of Official Notice, Applicants respectfully request such evidence or an affidavit according to rule 37 CFR 1.104(d)(2).

As an additional note; Applicants do note the recitation of MPEP 2144.03(D) in the Office Action, Page 9, fourth paragraph; however, also note that such would be improper here as there has not yet been any determination as to how, from where or why there might be a teaching, suggestion or motivation for the combination of any of the current references with the as-yet to be determined reference on miniaturized PCR. How or why would any skilled artisan be taught, suggested or motivated to move from generic miniaturized PCR to an application such as that claimed here; particularly how are we to know if this suggestion/motivation is in the art if the art has not yet been cited? The teaching, suggestion or motivation must also be found in or demonstrated from the art. As it has not, a final rejection would be premature.

The rejections of claims 3, 4, 7-9, 13-15 and 18 are thus obviated and/or traversed and can and should be withdrawn. Action to this end is respectfully requested.

Claims 5, 6, 10-12 and 16

Lastly, claims 5, 6, 10-12 and 16 stand rejected under 35 USC §103(a), as purportedly being obvious over Huang, Birmingham, and Mainelis and further in view of Braven.

As was the case for Johns above, Braven also fails to cure the lackings of Huang to disclose a first and second electrode, a distance of at most 20 mm between the first and second electrode; electrostatic collection of particles from a gaseous sample; a gaseous sample; contacting electrostatically collected biological particles with the first liquid reagent; or the concept of electrostatically collecting and lysing the biological particles in the same chamber, or of Birmingham to provide an electrode defined electric field and/or a liquid reagent. Moreover, as before, there is no motivation for making any substitution or other change in either Huang, Birmingham or Mainelis using Braven. Indeed, as described in detail with regard to Mainelis above; such discussion is incorporated herein as if fully set forth here; any generalized motivation for wanting portable devices for sensitive detection is not sufficient for the teaching/suggestion/motivation test in that such motivation says nothing about the specific alteration or substitution which is suggested to or should be effected in the base apparatus or system. In other words, it is not clear from such a generalized motivation what would/should be changed in either the Huang or Birmingham system nor how such would be achieved. This is thus an improper basis for alleging a combination of Braven with any of Huang, Birmingham and/or Mainelis. Applicants' claims thus define thereover.

The rejections of claims 5, 6, 10-12 and 16 are thus obviated and/or traversed and can and should be withdrawn. Action to this end is respectfully requested.

Double Patenting – Obviousness Type

Terminal disclaimers will be filed upon notification of allowable subject matter.

CONCLUSION

Applicants note that all rejections are obviated or traversed and respectfully request that they thus be withdrawn. A timely Notice of Allowance is requested to be issued in this case. Applicants believe that no fees or petitions, other than the extension fee/petition set forth above, are due with this filing. However, should any such fees or petitions be required, please consider this a request therefore and authorization to charge Deposit Account No. 02-2093 as necessary.

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Respectfully submitted,

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